

16024 Phoebe Avenue, La Mirada, CA 90638-5585

Office of Nutritional Products
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Pkwy.
College Park. MD 20740

MAY 2 5 2004

RE: Notification of statements on a dietary supplement known as, Acid Redux™ Nighttime tablets

May 13, 2004

Dear Ladies/Gentlemen;

Pursuant to 21 C.F.R. Subpart F, section 101.93, Nutri Granulations, the distributor of Acid Redux™ Nighttime Tablets, which is located at 16024 Phoebe Avenue, La Mirada, CA 90638-5585, wishes to notify the Food and Drug Administration that it intends to begin marketing a dietary supplement known as Acid Redux™ Nighttime tablets which include statements of nutritional support in its labeling. Acid Redux™ Nighttime tablets are to be marketed under the brand name of Clinic®.

The following statements are being made for the dietary supplement known as Acid Redux™ Nighttime tablets:

- Acid Redux™ Nighttime tablets comfort the digestive system, and assist in maintaining a proper body pH.
- Acid reducing dietary supplement comforts the digestive system.

The name of the dietary ingredient that is the subject of the above statements is Calcium Carbonate.

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The above statements are accompanied by the required disclaimer, which is prominently displayed in boldfaced type, directly following each statement with no intervening material. The disclaimer appears on each panel where the statements occur.

The information contained in this notice is complete and accurate. Nutri Granulations maintains on file scientific substantiation that these statements are truthful and non-misleading.

An original and two copies of this notification are being submitted.

Sincerely,

Alan E. Huffington

Director of Regulatory Affairs (714) 994-7863 Desk phone (714) 393-6656 Cell phone ahuffington@nutrigran.com

Enclosures: Two copies of this two-page letter.

CC: Kevin Salerno
President
Nutri Granulations

Kurt Schneider Vice President and General Manager Nutri Granulations